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March 3, 2016

Committee on Finance

United States Senate

RE: Pubic comment High priced drugs

Dear Senator Wyden and Senator Grassley,

Caring Ambassadors Program is a National non –profit agency based in Oregon City, Oregon serving people with hepatitis c and lung cancer.

Before responding to your questions I would like to express my disappointment that the committee choose to investigate the one drug that represents an easy, non-toxic CURE to the disease that is the largest infectious disease outbreak in America in our lifetime to highlight the problems of all drug pricing. However, as Co-Chair of the HCV Fair Pricing Coalition, I was the first person to tell Gilead that Oregon Medicaid, in particular, would not pay for their drug unless it was reasonable priced, despite the fact that Oregon's death rate is higher than the rest of the country. The investigation and subsequent report has had profound negative impact on access to the cure for hepatitis C for a majority of people. Medicaid programs in many states and private insurance companies have felt empowered to discriminate against a disease because of this investigation. The discrimination has no medical basis and CMS has subsequently sent out a letter to all states warning of the illegality of their actions. Washington State has seen 2 lawsuits filed already. Oregon Medicaid has implemented draconian restrictions opening up the state to lawsuits which will benefit no one, and cost the state and tax payer's significant dollars.

While you continue to find long term solutions for all drug costs, we need your help to find immediate solutions to address the HCV public health crisis.

1972. Continued Rising Mortality from Hepatitis C Virus in the United States, 2003-2013

October 7-11 • San Diego, CA • www.idweek.org
IDWeek 2015
Advancing Science, Improving Care

Part of Session: 273. The Spectrum of Viral Infection

2:00 p.m.

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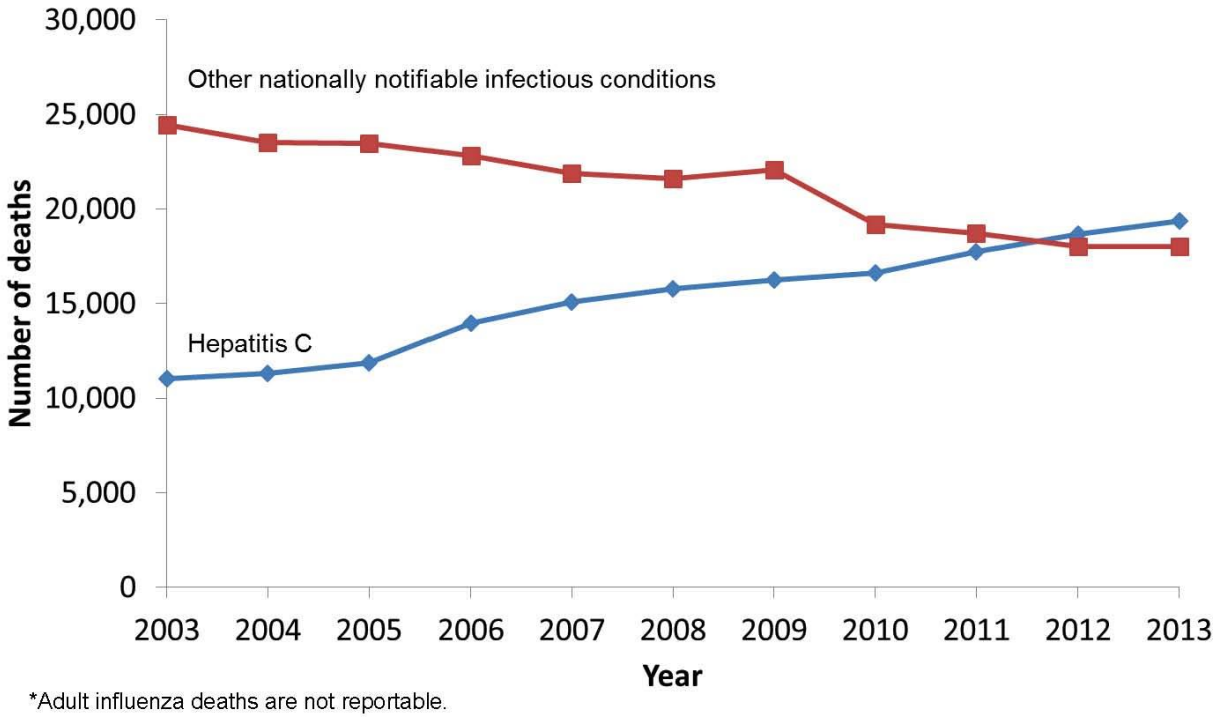
Background: Despite new curative antiviral treatments for hepatitis C virus (HCV) infection, the increasing mortality and health burden for HCV-infected persons remain underappreciated. We examined national multiple-cause-of-death (MCOD) data from 2003-2013 and data from the Chronic Hepatitis Cohort Study (CHeCS) to estimate trends in HCV–related mortality in the United States.

Methods: ICD-10 codes in the MCOD 'record axis' fields were examined for hepatitis C and 59 other nationally notifiable (to CDC) infectious conditions. To calculate mortality rates in MCOD data, deaths associated with HCV infection and the other infectious conditions were divided by the US Census population for each year or, for CHeCS, by the numbers of HCV-infected persons in the cohort in each year.

Results: From 2003-2013, deaths with hepatitis C recorded on death certificates increased from 11,051 in 2003 to 19,368 in 2013 (**Figure;** Cochrane-Armitage trend test, p=0.01), while deaths associated with all 59 other notifiable infectious conditions decreased from 24,434 in 2003 to 18,002 in 2013 (**Figure,** trend, p=0.06). In 2012, the number of deaths associated with hepatitis C surpassed that with all 59 other notifiable infectious conditions. In 2013, 51.1% (n=9,899) of HCV-related deaths occurred among persons aged 55-64 years (mean age, 59.7 years). Declining mortality trends were observed in 11,000 HCV-infected persons in care in CHeCS.

Conclusion: Despite improving therapies, deaths from hepatitis C—mainly among persons aged 55-64 years-- continue to rise, indicating the poor penetrance of therapies to the 3 million Americans estimated to be infected with HCV. Moreover, since only 19% of HCV-infected patients who die have HCV listed anywhere on their death certificate, these data underestimate the problem.

Figure. Annual number of deaths from hepatitis C virus and 59 other nationally notifiable infectious conditions listed as multiple causes of death in the United States, 2003-2013.*



*Adult influenza deaths are not reportable.

1. What are the effects of a breakthrough, single source innovator drug on the marketplace?

Single source breakthrough drugs will be expensive. America is based on capitalist society. Until healthcare is a right, and we have a single payer system there will be NO significant changes made on our current broken healthcare system. Drugs are developed at a huge cost, the majority never leave the lab. Investors will not invest in the development of drugs unless they see financial gain in the long run. Luckily, competition generally is close behind which will bring prices down just as we have seen with the new Direct Acting Antivirals for hepatitis C.

2. Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

Yes, they do. In the case of HCV they knew 3 years before the drug was approved that it could cost up to 100K and that is was worth it because of the costs of living and subsequently dying with hepatitis C. At the time Interferon based therapy was ~ 187K per cure.

CDC has not hidden the numbers of people living with hepatitis C. Insurance companies knew how many people need treatment. They have kept them off of plans for years because of pre-existing conditions.

Fifteen years ago I met with a former CMS insider and was told that they did not want people to be cured because then Medicare would have to cover the expense of old age and heart disease etc… Given the treatments available at the time, they predicted many of the baby boomer population would die before reaching Medicare eligibility. At the same meeting an ex-head of large private insurance company said they did not encourage testing because they would be stuck with that person (he actually said "trash") since at the time you did not want to change plans if you had a pre-existing condition. Their actuaries figured the cost of dying from liver disease or liver cancer would fall on Medicare.

3. What role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price?

If a disease is an infectious disease and can be cured then there is no debate of its value. However it must be priced so there is access for all of those infected with the ultimate goal of elimination of a disease.

Oncology drugs have been high priced for decades and most do not offer a cure, some only offer a few weeks of extra life. This is where the value needs to be negotiated by CMS with the manufacturers.

4. What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

Manufactures should have to disclose actual development costs when a drug reaches a certain threshold. Payers should also have to disclose the actual price they are paying.

5. What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

a.) Native Americans are highly impacted by HCV. Native Americans have twice the morbidity than Caucasians from HCV. The tribes should be able to import generics as they are sovereign nations. Policies would have to be put into place to allow state licensed pharmacists to dispense the drugs to the tribes. IHS should make an emergency declaration for immediate implementation.

b.) Medicaid expansion programs or CCO's should be able to purchase under 340b pricing.

c.) Allow states to carve out HCV drugs on their formularies so they do not affect the 2% increase they need to maintain per ACA. This could have a sunset date to encourage treatment.

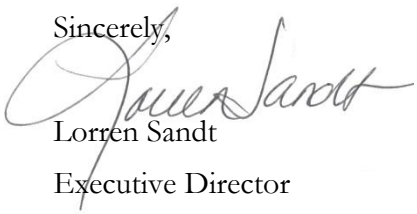
d.) Allow CMS to negotiate a price for all state programs.

e.) Allow Medicaid, correctional facilities and managed care programs to have the same purchasing program as the VA.

f.) Implement a single payer system.

We appreciate your request for input into this important topic. We encourage you to look at all drugs and not allow hepatitis C to be the poster child. Solvaldi is not even close to be the most expensive drug. Currently, the therapies are not only cost effect, they are cost saving. No other disease has had to show cost saving in order for the cure to be a part of standard of care. We encourage you to work with CMS to stop the current restrictions and be part of the solution in a United States Elimination Plan of HCV.

Sincerely,



Lorren Sandt

Executive Director